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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,323	01/25/2002	Harry R. Davis	CV01489K	1525

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

BAHAR, MOJDEH

ART UNIT PAPER NUMBER

1617

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/057,323

Applicant(s)

DAVIS ET AL.

Examiner

Mojdeh Bahar

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-101 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-34, 37-40, 42-48, 53-54, 56, 58-59, 61, 63-64, 66, 68-69, 71, 73-74, 76, 78-79, 81, 83-84, 86, 88-91, 93-101, drawn to compositions comprising at least one peroxisome proliferators-activated receptor activator, at least one sterol absorption inhibitor and an optional third active such as HRT, lipid lowering agents, fatty acids, vitamins, diabetes treating agents, classified in class 514, subclasses 210, 555, 169, 170, 171, 558, 423, 311, 460, 510, 356, 276, 251, 725, 458, 474, 3 for example.
- II. Claims 35-36, 41, 49-52, 55, 57, 60, 62, 65, 67, 70, 72, 75, 77, 80, 82, 85, 87, and 92, drawn to a method of treating or preventing vascular condition, diabetes, obesity employing a composition comprising at least one peroxisome proliferators-activated receptor activator, at least one sterol absorption inhibitor and an optional third active such as HRT, lipid lowering agents, fatty acids, vitamins, diabetes treating agents, classified in class 514, subclasses 210, 555, 169, 170, 171, 558, 423, 311, 460, 510, 356, 276, 251, 725, 458, 474, 3 for example.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case diabetes can be treated by insulin alone, vascular conditions can be treated with antihypertensive agents alone, obesity can be treated with anorectics alone.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Specie Election

Claims 1-101 are generic to a plurality of disclosed patentably distinct species comprising:

- Peroxisome proliferator receptor activators
- Sterol absorption inhibitors
- A third therapeutic agent, e.g., lipid lowering drugs, antioxidants, fatty acids, vitamins, HRT, diabetes treating agents

The claims as presented contain such vast multitude of “possibilities and permutations” for different species of each of the above therapeutic agents and possible combinations of these species in the instant compositions and methods that the search for all is considered an undue burden on the office. The diversity of species in these claims can be illustrated by their different classifications. Claims 1-101 are classified in subclasses 210, 555, 169, 170, 171, 558, 423, 311, 460, 510, 356, 276, 251, 725, 458, 474, 3 of class 514, for example. The search for all species and all possible combinations constitutes a burden to the office. Note that search is not limited to patent files.

Applicant is required to elect a specific specie (i.e., one single compound) for each of the above three active agents for examination purposes. A specific specie is a compound

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wherein all the substituents are clearly defined. Applicant is advised that the response to this requirement must include an identification of the species that is consonant with the requirement set forth in 35 U.S.C. 121 as well as a **listing of all claims readable thereon**.

Claims 35-36, 41, 49-52, 55, 57, 60, 62, 65, 67, 70, 72, 75, 77, 80, 82, 85, 87, and 92 are generic to a plurality of disclosed patentably distinct species comprising diseases, e.g. vascular disease, diabetes, obesity. **Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e., one single condition), even though this requirement is traversed.**

While insulin is readily used in treating diabetes, vascular disease and obesity are not treated with insulin. Heparin or Aspirin are employed in methods of treating/preventing vascular conditions, but they are not employed in treating diabetes. Finally, anorectics are employed in treating obesity, but are not routinely employed in treating vascular conditions. The treatment of each of these diseases represents a separate field of medical technology having a separate field of search. The search for treatment of all of these diseases is therefore an undue burden on the office. Note that the search is not limited to patent files.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Because the above restriction/election requirement is complex, a telephone call to the applicant's agent to request an oral election was not made. See M.P.E.P. Sec 812.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday to Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
June 30, 2003



SREENI PADMANABHAN
PRIMARY EXAMINER

6/30/03